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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,614	03/01/2000	GAIL PETUNA RISBRIDGER	229752000800	6186

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EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/18/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/402,614

Applicant(s)

RISBRIDGER ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 40-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 40-57, 59, 61 and 64-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58, 60, and 62-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

The Amendment filed September 26, 2002 (Paper No. 13) in response to the Office Action of March 26, 2002 is acknowledged and has been entered.

Claims 1-26, and 40-67 are pending in the application.

Claims 1-26, 40-57, 59, 61, 64-67 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. (It is noted that in the "Version with Markings to Show Changes Made" applicants requested Claims 1-57, 59, and 64-67 be cancelled". However, such a request was not made in the amendments to the claims. It appears that applicants only requested that claims 58, 60, and 63 be amended on page 3, of Paper No. 13. Thus, claims 1-57, 59, and 64-67 have not been cancelled.)

Claims 58, 60, and 62-63 are currently under prosecution.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 58, 60, and 62 remain rejected under 35 U.S.C. 102(b) as being anticipated by *Teni et al.* (Clinical Chemistry, Volume 35, No. 7, pages 1376-1379, 1989) for the reasons of record in Paper No. 12, pages 4-5).

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Applicants argue (Paper No. 13, page 5) that the prior art does not anticipate the claimed invention of screening for “inhibin protein” since the prior art only discloses measuring the level of the prostatic *inhibin-like* protein (PIP). Applicants further argue that the term “inhibin-like” is not actually an inhibin. This argument has been considered but is not found persuasive. As mentioned in the previous action, the specification broadly defines the term “inhibin”. This includes fragments, said fragments having the functional activity of inhibin and further includes homologues, analogs, mutants, variants and derivatives thereof (specification, page 7, lines 5+). Thus, broadly interpreted, a prostatic inhibin-like peptide (i.e. PIP) is a fragment, variant, or derivative of inhibin. Applicants further argue (Paper No. 13, page 5) that they have submitted an abstract of an article (Gordon *et al.*) which explicitly states that “ $\beta$ -microsemenoprotein is not an inhibin”. This argument has been considered but is not found persuasive because no such article accompanied applicant’s response. Secondly, the argument appears irrelevant because applicants have not established a relationship between the prior art teaching of PIP and a “ $\beta$ -microsemenoprotein”. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

Claims 58, 60, 62-63 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ying *et al.* (Life Sci. Volume 60, Number 6, pages 397-401, January 1997, IDS, #47) and Teni *et al.* (Clinical Chemistry, Volume 35, No. 7, pages 1376-1379, 1989) for the reasons of record in Paper No. 12, pages 6-7.

Applicants argue (Paper No. 13, page 6), that as discussed above, the Examiner’s reliance upon Teni as showing the successful screening of prostate comprising screening for the down

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regulation of inhibin protein levels is erroneous because Teni doe not disclose screening for an inhibin as claimed. This argument has been considered but is not found persuasive for the reasons set forth above concerning the 102(b) rejection. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

**New Rejections:**

Claims 58, 60, 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the claims are vague because there is no limit to what encompasses a "modified" inhibin. Thus, it would not be clear how the modification indicates the presence or absence of prostate cancer. Also, in claim 63, the modification is "absent". Absent what? The claims clearly do not indicate what the modification is in relationship to, and therefore the presence or absence of such a modification is vague. As such, the metes and bounds of the claims cannot be determined.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

No claim is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Gary B. Nickol Ph.D.

Examiner

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GBN

December 13, 2002

  
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